Serial No.: 09/936,098
Docket No.: VAS-5395
Amendment dated February 2, 2004
Responsive to Office Action of December 2, 2003

REMARKS/ARGUMENTS

Prior to the present Office Action, claims 1-6 were pending. Claims 1-6 have been canceled. Claims 7-28 had been added and are therefore pending.

The objection to claims 2 and 3 under 37 C.F.R. §1.75(c), and the rejection of claim 2 under 35 U.S.C. §112 are obviated by cancellation of these claims.

New claim 7 provides a directable medical guidewire having a main portion and a distal end portion with two curved sections: a first section having a first curvature and a second section located distally with respect to the first section and having a second curvature different to that of the first section.

The pending rejections in the Office Action will be discussed with respect to the new claims.

Discussion of Claim Rejections on the Basis of Wisselink

Claims 1-6 stand rejected under 35 U.S.C. §102(e) as being anticipated by Wisselink (USPN 5,984,955). Wisselink discloses a system for endoluminal grafting of bifurcated or branched vessels which utilizes a straight guidewire 30 extending up through one iliac artery and being diverted by a curved guide catheter 68 into the other iliac artery. Please see the description at Col. 10, lines 19-42, as follows:

> With reference to the step-wise showings of FIGS. 2a-2c, the preferred method comprises the steps of:
>
> 1. Forming an access opening 66 into one of the femoral arteries F, and advancing a guidewire 30 through such access opening 66, through the contiguous iliac artery IL_1, and into the aorta A;
>
> 2. Advancing the bifurcated primary graft 12a over the guidewire 30, and positioning the primary graft 12a in the aorta A and first iliac artery IL_1 such that its branch graft opening 14a is directed toward the other iliac artery IA_2, as shown in FIG. 2a;

3. Causing the primary graft anchoring device 18 to hold at least the superior end of the aortic portion 60 of the primary graft 12a in the aorta A, and the inferior end of the iliac portion 62 of the primary graft 12a in the first iliac artery IA_1;

4. *Advancing a curved guide catheter 68*, having an angle of curvature AC less than 90 degrees, into the lumen of the aortic portion 60 of the primary graft 21a;

5. *Advancing the guidewire 30 through the guide catheter 68, such that the distal end of the guidewire 30 passes out of the distal end of the curved guide catheter 68 and into the other iliac artery IA_2 ;* (emphases added)

There is no disclosure or suggestion in Wisselink to provide other than a conventional, straight guidewire 30. The figures show the guidewire been deflected by the curved guide catheter 68. Without this guide catheter, the guidewire 30 would continue in its straight configuration upward through the ascending aorta. Accordingly, claim 7 is believed allowable over Wisselink.

Discussion of Claim Rejections on the Basis of Dehdastian, et al.

Claims 1-6 stand rejected under 35 U.S.C. section 102(e) as being anticipated by Dehdastian, et al. (USPN 6,451,053). Dehdastian, et al. disclose a system for intraluminal placement of a bifurcated graft. The "primary guidewire 128" referenced by the Examiner is straight and there is no mention of distal curves, or any curves in the guidewire for that matter. Dehdastian, et al. also use a directional catheter to re-direct a straight guidewire 228 (or "stiffer guidewire 228a") from one iliac artery into another. Please see the description at Col. 26, lines 17-58, as follows:

More particularly, the directional catheter 220 is first inserted over the primary guidewire through the ipsilateral side, for example, through the right femoral artery 116 and the right common iliac artery 102 in the present case. FIG. 13A illustrates the directional catheter 220 operatively connected to the sheath assembly 132. The spring portion 222 of the directional catheter 220 is positioned such that it is above the septal region 28 of the aortic graft 10. Proper positioning of the spring portion to the contralateral side is adjusted by rotating or advancing forwards or backwards the whole directional catheter 220 while under fluoro-visualization. The spring portion 222 is deflected by pulling knob

224 in the direction of the arrow in FIG. 13A. FIG. 13B illustrates the deflected spring portion 222 positioned within the contralateral leg 14.

A supplemental guidewire 228 is then advanced through the directional catheter 220 and out the deflected spring portion 222 to extend down the contralateral leg 14 and through the left common iliac artery 104. The supplemental guidewire 228 is extended until it is in the left femoral artery 118, at which time the left femoral artery is cross-clamped and a cut-down or percutaneous incision is performed to retrieve the supplemental guidewire. If the guidewire has not been guided fully along the femoral artery a snare or similar device can be introduced through the left femoral artery to grab the guidewire and draw it back to the puncture or incision site for retrieval.

As seen in FIG. 13C, once the supplemental guidewire 228 is in place through the left common iliac artery 104 the directional catheter 220 is advanced distally through the bifurcated graft 10 and into a position above the renal arteries 106, 108. The spring portion 222 remains deflected to present a curvilinear upstream profile. This curved profile enables advancement of the directional catheter 220 without risk of the distal end of the spring portion 222 snagging on the openings to the renal arteries 106, 108. The directional catheter 220 remains in this position while the tubular graft extension 170 is attached to the contralateral leg 14. *A stiffer guidewire 228a is then exchanged with the supplemental guidewire 228 by conventional methods to extend through the left iliac artery 104 and within the contralateral leg 14 of the aortic graft.* (emphases added)

Therefore, Dehdastian, et al. does not disclose nor suggest a curved guidewire as provided in new claim 7, and claim 7 is believed allowable thereover.

Dependent Claims

A number of dependent claims provide features that are not disclosed or suggested by the cited references. For example, a straight intermediate section between curved sections is not disclosed in the cited references. Further, the cited references do not provide for circular or elliptical curves. In short, there are numerous other features and combinations present in the claims that are believed patentable over the cited references.

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Conclusion

In accordance with the foregoing remarks and amendments, claims 7-28 are believed to be in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged to contact the undersigned by telephone.

Respectfully submitted,

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Guy Cumberbatch, Reg. No. 36,114
Telephone: (773) 857-7634
c/o Lena Vinitskaya, Reg. No. 39,448
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer No. 30452